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February 27, 2006

The Hon. Kent A. Jordan
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844 N. King Street
Room 6325, Lockbox 10
Wilmington, DE 19801

REDACTED VERSION

RE: *In re Tricor Direct Purchaser Antitrust Litig.*, C.A. No. 05-340 (KAJ).

Dear Judge Jordan:

I am writing on behalf of Coordinated Direct Purchaser Plaintiffs ("Plaintiffs") in accordance with paragraph 6(h) of the Court's Scheduling Order of October 27, 2005, regarding discovery disputes. This dispute is framed by Plaintiffs' First Set of Request for Production Nos. 78-83, and Defendant Abbott's responses and objections thereto, attached as Exhibit "A".

The instant discovery dispute involves a single issue: Defendant Abbott's refusal to produce documents related to the purpose and effect of its conversion of the markets for Hytrin and Tranxene from one dosage form to another. Plaintiffs expressly allege that the Hytrin and Tranxene conversions are highly relevant to this case because, *inter alia*, Defendants used these conversions as models for their illegal scheme to maintain their fenofibrate monopoly by impeding generic competition to Tricor. *See* Direct Purchaser Class Plaintiffs' First Amended and Consolidated Class Action Complaint ("DPC Cpt.") at ¶ 116. Thus, Abbott's documents regarding the Hytrin and Tranxene conversions are clearly relevant to Plaintiffs' claim that Defendants acted with anticompetitive intent in similarly developing medically equivalent (but non-AB-rated) dosage forms of Tricor, and converting Tricor demand to the dosage form not facing imminent generic competition, in order to impede generic competition.

Likewise, these documents are clearly relevant to assessing the credibility of Defendants' claims that tablets are better than capsules – and thus that their switch from Tricor capsules to tablets constituted a product "improvement" – because, for instance, Abbott switched Hytrin away from a tablet to a capsule. *See* Defendants' Consolidated Opening Brief in Support of Motion to Dismiss ("Defendants' Opening MTD Brief") at p. 12. Plaintiffs are clearly entitled to discovery regarding these types of tablet-to-capsule conversions in order to rebut Defendants' claims that tablets are superior to capsules, and to corroborate Plaintiffs' allegations that the direction of Abbott's "product hopping" (as Professor Hovenkamp calls it)[1] was dictated not by

[1] Hovenkamp, *et al., IP and Antitrust: An Analysis of Antitrust Principles Applied to Intellectual Property Law*, 2006 Supp. at sec. 12.5.

whether tablets were better than capsules, but rather by whether Abbott faced imminent generic competition from tablets (as with Hytrin) or capsules (as with Tricor).

As detailed in Plaintiffs' opposition to Defendants' Motion to Dismiss, a key component of Defendants' multi-faceted exclusionary scheme was the development of new versions of Tricor that would not be AB-rated to its prior versions. *See* Direct Purchaser Plaintiffs' Answering Brief in Opposition to Defendants' Consolidated Motion to Dismiss ("MTD Opp.") at p. 2. That is because, as Defendants well knew, under the statutory regime governing generic drugs (in particular, the provisions of the Drug Product Selection laws and the Hatch-Waxman Act intended to promote generic substitution (*Id.* at 6-11)), (1) AB-rated generics can be substituted for their brand-name counterparts by pharmacists without the prescribing doctors' permission, while (2) non-AB-rated generics cannot be substituted for the brand without a new prescription. Therefore, by developing new non-AB-rated tablet versions of Tricor, switching demand for Tricor to those new versions, and killing the market for the prior capsule version of Tricor before generic manufacturers could obtain FDA approval to sell their generic version of the capsules, Defendants knew they could preclude generic capsules from effectively competing with Tricor -- even where, as here, the tablet versions of Tricor are medically identical (and bioequivalent) to the capsule form.[2]

One of the ways that Defendants chose to gain FDA approval for a non-AB-rated version of Tricor that they could use to impede generic competition, was to change its dosage form -- in this case, from a capsule to a tablet. Applicable FDA regulations provide that a generic must contain the same dosage form, as well as the same active ingredient, as the brand in order to be AB-rated to the brand. MTD Opp. at 7, citing DPC Cpt. at ¶ 41. Defendants clearly knew that this ploy could succeed in impeding generic competition for Tricor because Abbott had used the same ploy at least twice before to impede generic competition for the branded drugs Hytrin and Tranxene.

Despite the obvious similarities between the alleged Tricor scheme and the Hytrin/ Tranxene schemes, Abbott baldly claims that the Hytrin/Tranxene schemes are completely irrelevant to this case. Defendant Abbott is wrong for several reasons. First, as explained above, the details of the Hytrin/Tranxene conversions are clearly relevant to Plaintiffs' allegations that Defendants knew, based largely on the success of the Hytrin/Tranxene conversions that preceded the Tricor conversions, that they could thwart generic competition for Tricor by similarly switching market demand to a dosage form that was not AB-rated to the versions of Tricor for which their generic competitors had pending Abbreviated New Drug Applications. *See, e.g.,* DPC Cpt. at ¶¶ 116-117.[3]

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[2] Indeed, because of the success of Defendants' exclusionary scheme in this case, generic versions of Tricor achieved only 5% of fenofibrate sales, as opposed to the 70-80% (or more) typically achieved by AB-rated generics promptly upon generic entry.

[3] Plaintiffs have expressly alleged that Abbott used a product-hopping strategy to impede generic competition for Tranxene, as well as Hytrin. *Id.* Defendants have not denied or rebutted this allegation.

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Likewise, as explained above, the requested Hytrin (and Tranxene) documents are highly relevant to Defendants' primary defense -- that the "new" Tricor tablets constituted an "improvement" over the old capsule form because, *inter alia*, tablets are better than capsules. This is because the Hytrin conversion was in the exact opposite direction as the Tricor conversion – *i.e.*, from a tablet to a capsule. Plaintiffs contend that Abbott's switch away from a tablet in Hytrin -- because in that case, the imminent generic threat was from a tablet form, rather than a capsule, which was the imminent threat in this case -- seriously undermines Defendants' claim that their switch to a tablet form of Tricor constituted a product improvement, and supports Plaintiffs' allegation that the direction of Abbott's product switches is dictated by a desire to impede generic competition, rather than any legitimate effort to "improve" the Tricor product.

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. This is particularly true considering that Fed.R.Civ.P. 26(b)(1) provides a broad scope of discovery generally (*Advanced Medical Optics, Inc. v. Alcon*, 2004 WL 1877724 (D. Del. 2004)) and there is a general policy of liberal discovery in antitrust cases (*Kellam Energy, Inc. v. Duncan*, 616 F. Supp. 215 (D. Del. 1985)). "Particularly where allegations of conspiracy or monopolization are involved, as in the instant case, broad discovery may be needed to uncover evidence of invidious design, pattern or intent." *Kellam Energy,* 616 F. Supp at 217.

In light of the above, Plaintiffs' respectfully request that the Court compel Abbott to produce documents related to their conversions of Hytrin and Tranxene as requested in Document Request Nos. 78-83.

Thank you for your consideration of this matter.

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Respectfully submitted,

Jeffrey S. Goddess (Del. Bar No. 630)

cc: All counsel of record on attached service list

EXHIBIT A

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

IN RE TRICOR DIRECT PURCHASER ANTITRUST LITIGATION	C.A. No. 05-340 (KAJ)
	(consolidated)
THIS DOCUMENT RELATES TO:	
ALL ACTIONS	

ABBOTT LABORATORIES' RESPONSES TO DIRECT PURCHASER PLAINTIFFS' FIRST SET OF DOCUMENT REQUESTS (NOS. 1-85)

Abbott Laboratories ("Abbott"), responds to Direct Purchaser Plaintiffs' ("Plaintiffs") First Set of Document Requests (No. 1-85) to Abbott Laboratories as follows:

GENERAL OBJECTIONS

Abbott incorporates the following General Objections into each of its responses to Direct Purchaser Plaintiffs' Requests:

1. Abbott objects to Plaintiffs' Requests to the extent that they call for documents protected by the attorney-client privilege, documents prepared in anticipation of litigation or for trial, or otherwise protected from discovery by the attorney work-product doctrine or any other applicable privilege or immunity. Should any response by Abbott include such privileged or protected documents, such disclosure is inadvertent and shall not constitute a waiver of any privilege or of any other ground for objecting to discovery with respect to such documents, or any parts thereof, or of Abbott's right to object during this litigation or otherwise to the use of any such documents or any parts thereof.

2. Abbott objects to Plaintiffs' Requests to the extent that: (a) the discovery sought by any such request is unreasonably cumulative, duplicative, redundant or is obtainable

market studies conducted by Abbott that compare Abbott's actual or anticipated sales and profits for the products marketed under NDA 19-304, NDA 21-203, and NDA 21-656.

78. All documents relating to any decision to develop, seek FDA approval for, scale up, manufacture, market and/or promote a new dosage form and/or formulation of a pharmaceutical product already sold by you, including but not limited to Hytrin and Traxene, including but not limited to documents concerning:

(a) any actual, potential or claimed benefits of one dosage form and/or formulation over another;

(b) whether to cease sales, marketing and/or promotion of one or more dosage forms and/or formulations; and

(c) any surveys of pharmacists, doctors and/or other health professionals done in connection with the development, marketing, launch and/or promotion of a new dosage form and/or formulation of a pharmaceutical product already sold by you.

RESPONSE

In addition to its General Objections, Abbott objects to this Request as overly broad and unduly burdensome because it calls for "all documents." Abbott also objects to this Request to the extent that it calls for documents protected by the attorney-client privilege, work product doctrine, and/or confidentiality obligations to third parties. Abbott also objects to this Request as unreasonably cumulative, duplicative, and redundant. Abbott objects to producing confidential information unrelated to the products marketed under NDA Nos. 19-304, 21-203, or 21-656 because such information is not relevant to any claim or defense in this lawsuit. Without waiving any objections, to the extent that such documents exist and are in Abbott's possession, custody, or control, Abbott will produce documents sufficient to show its development and marketing plans for the TriCor® formulations corresponding to NDA No. 21-203 and/or NDA No. 21-656.

79. All documents (including but not limited to analyses, projections, and/or forecasts) relating to any and all actual and/or projected effects on sales, revenues, costs, and/or

profits of developing, formulating, scaling up, manufacturing, producing, marketing, and/or selling a new dosage form and/or formulation of a pharmaceutical product already sold by you,

RESPONSE

See Objections and Response to Request No. 78.

80. All documents (including but not limited to analyses, projections, and/or forecasts) relating to any and all actual and/or projected effects on efficiencies, economies of scale and/or scope, and/or production capacity, relating to the development, production, marketing, and/or selling (and/or the cessation and/or reduction of production, marketing, selling and/or availability) of a new dosage form and/or formulation of a pharmaceutical product already sold by you.

RESPONSE

See Objections and Response to Request No. 78.

81. All documents (including but not limited to analyses, projections, and/or forecasts) relating to any and all actual and/or projected effects on revenues, costs, and/or profits, relating to converting sales, prescriptions, and/or market demand from one formulation and/or dosage form of a pharmaceutical product sold by you to another version of such product,

RESPONSE

See Objections and Response to Request No. 78.

82. All documents relating to any and all actual and/or projected effects on revenues, costs, and/or profits, relating to converting sales, prescriptions, and/or market demand from one formulation and/or dosage form of a pharmaceutical product sold by you to another version of such product.

RESPONSE

See Objections and Response to Request No. 78.

83. All documents regarding any actual, projected and/or claimed benefits, harms, similarities and/or differences between capsule and tablet formulations of the same pharmaceutical product.

RESPONSE

See Objections and Response to Request No. 78.

84. All documents related to the therapeutic equivalence of the pharmaceutical products described and/or approved in: (a) NDA 19-304 and NDA 21-203 ; (b) NDA 19-304 and NDA 21-656; and (c) NDA 21-203 and NDA 21-656, including but not limited to:

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November 4, 2005
491341

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I hereby certify that on November 4, 2005, I caused the foregoing to be served upon counsel of record in the manner indicated:

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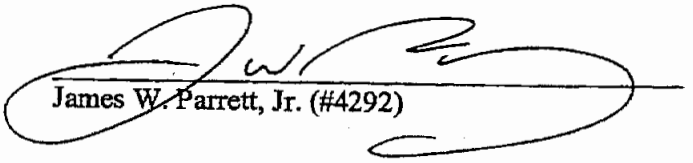

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491341

EXHIBIT B

REDACTED

EXHIBIT C

REDACTED

CERTIFICATE OF SERVICE

I hereby certify that on March 9, 2006, I electronically filed the foregoing REDACTED LETTER TO THE HON. KENT A. JORDAN (D.I. 89) using CM/ECF, which will send notification of such filing to all registered participants, including:

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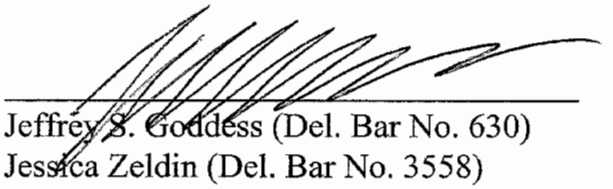

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